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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,082	10/06/2003	Jacobus M. Lemmens	091856-0105	4414
22428 7590 05/11/2010 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007				
EXAMINER				
SIMMONS, CHRIS E				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
05/11/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/678,082

**Applicant(s)**

LEMMENS ET AL.

**Examiner**

CHRIS E. SIMMONS

**Art Unit**

1612

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 51-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/22)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' arguments, filed 11/20/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### **Obviousness Rejection**

Claims 51-59 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Pathak et al. (USP 6,113,944) in view of Benneker et al. (USP 5,874,447) and Chu (USP 4,675,188).

Applicant argues that the prior art does not teach or suggest the instant composition that has a pH within the range of 5 to 6. Applicant also submits that the prior art does not teach or suggest that pH is a parameter to be adjusted, much less adjusted to recite the range of 5 to 6. Applicant alleges that the reference to pH in the Chu reference is made in a completely different context from the presently recited pH. Accordingly, applicant asserts that it would not have been obvious to adjust the pH.

The examiner contends that, the pH is a property of the composition and a prima facie case of either anticipation or obviousness can be established where

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the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes. In this case, the prior art suggest a composition that is substantially identical to that which is claimed. Since the ingredients in the compositions disclosed in the prior art are the same as what is claimed, then the compositions would reasonably be considered to have similar pH values unless otherwise proven.

Secondly, even if the pH would not be a characteristic of the substantially identical composition, the context of the pH as recited in the Chu reference is relevant in this case because it refers to the shape and size of the anhydrous dicalcium phosphate particles (instant claim 53) as being effected by pH. The size of anhydrous dicalcium phosphate particles is recognize as an important factor with regard to the compressibility of the tablets using dicalcium phosphate as a direct compression vehicle (col. 4, ll. 25-32). It has unexpectedly been found that the product of the Chu invention provided a surprising increase in compressibility even at low pressures. Accordingly, one of ordinary skill in the art making tablets containing dicalcium phosphate would find the disclosure of Chu relevant since it discloses how to optimize the compressibility of the composition to form tablets.

Applicant argues that the reference only characterizes the pH of the aqueous composition from which dicalcium phosphate is made and not the final pharmaceutical product. Applicant's assertion that the reference only refers to the pH of solutions made during the process of making the dicalcium phosphate

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crystals is not found to be persuasive. Since the reference does disclose the pH during the process of making the dicalcium phosphate crystals, then the final product is reasonably considered to maintain a similar - if not the same - pH when mixed with the active ingredients to form the tablet. The instant specification recognizes that the pH of the composition can be adjusted by proper selection of excipients. *See instant Specification at pages 7 and 8.* One excipient is dicalcium phosphate. Some forms and grades of calcium phosphate are acidic or neutral pH. The specification also recognizes that this lower pH can be due to the species of calcium phosphate as well as the treatment during processing of the material, such as in removing impurities/washing. Accordingly, applicant's arguments declaring the manner in which dicalcium phosphate is made has no bearing on the final dicalcium product is not found to be persuasive.

Further, as outlined above, the prior art suggest a composition that is substantially the same as the composition claimed. The characteristics are reasonably considered to be the same since the ingredients are the same unless shown otherwise. See MPEP Section 2112.01 [R-3]. Accordingly, the pH is still reasonably considered to be the same.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. E. S./

Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612